

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 39, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

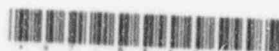
<p>Licensee</p> <p>1. Department of Health &amp; Human Services USPHS, NIH, NIAID</p> <p>2. Rocky Mountain Laboratories 903 South 4th Street Hamilton, Montana 59840</p>		<p>In accordance with letter dated March 18, 1997</p> <p>3. License number 25-01203-01 is amended in its entirety to read as follows:</p>													
		<p>4. Expiration date December 31, 2004</p>													
		<p>5. Docket or Reference No 030-05167</p>													
<p>6. Byproduct, source, and/or special nuclear material</p>	<p>7. Chemical and/or physical form</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p>													
<p>A. Any byproduct material with Atomic Numbers 1-83</p>	<p>A. Any except sealed sources</p>	<p>A. Not to exceed 50 millicuries per radionuclide except:</p> <table> <tr> <td>Hydrogen-3</td> <td>500 millicuries</td> </tr> <tr> <td>Carbon-14</td> <td>50 millicuries</td> </tr> <tr> <td>Chromium-51</td> <td>150 millicuries</td> </tr> <tr> <td>Iodine-125</td> <td>300 millicuries</td> </tr> <tr> <td>Phosphorus-32</td> <td>700 millicuries</td> </tr> <tr> <td>Sulfur-35</td> <td>80 millicuries</td> </tr> </table>		Hydrogen-3	500 millicuries	Carbon-14	50 millicuries	Chromium-51	150 millicuries	Iodine-125	300 millicuries	Phosphorus-32	700 millicuries	Sulfur-35	80 millicuries
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<p>B. Any byproduct material with Atomic Numbers 3-83</p>	<p>B. Sealed sources, plated sources, foils, or wires</p>	<p>B. Not to exceed 50 millicuries per sealed source, plated source, wire, or foil</p>													
<p>C. Cesium-137</p>	<p>C. Sealed sources (J. L. Shepherd Model 6810)</p>	<p>C. 2000 curies</p>													

9. Authorized use

- A. and B. For use in research and development as defined in Section 30.4 of 10 CFR Part 30, calibration of licensee's survey instruments, and academic instruction.
- C. For use in J. L. Shepherd Mark I Series, Model 30 Gamma Irradiator for irradiation of biological specimens.

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MATERIALS LICENSE  
SUPPLEMENTARY SHEET

License Number

25-01203-01

Docket or Reference Number

030-05167

Amendment No. 34

CONDITIONS

10. Licensed material shall be used only at the licensee's facility located at 903 South 4th Street, Hamilton, Montana.
11. A. Licensed material shall be used by, or under the supervision of, individuals designated by the licensee's Radiation Safety Committee, Dianne Huhtanen, Chairman.  
B. The Radiation Safety Officer for this license is Dianne Huhtanen.
12. A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as specified by the certificate of registration referred to in 10 CFR 32.210.  
B. Notwithstanding Paragraph A of this Condition, sealed sources and detector cells designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.  
C. In the absence of a certificate from a transferor indicating that a leak test has been made within 6 months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.  
D. Sealed sources need not be leak tested if:
  - (i) they contain only hydrogen-3; or
  - (ii) they contain only a radioactive gas; or
  - (iii) the half-life of the isotope is 30 days or less; or
  - (iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or
  - (v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

MATERIALS LICENSE  
SUPPLEMENTARY SHEET

License Number

25-01203-01

Docket or Reference Number

030-0517

Amendment No. 34

## 12. (Continued)

- E. The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30(b)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011, ATTN: Director, Division of Radiation Safety and Safeguards. The report shall specify the source involved, the test results, and corrective action taken.
- F. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to Perform such services.
13. Maintenance, repair, cleaning, replacement, and disposal of foils contained in detector cells shall be performed only by the device manufacturer or other persons specifically authorized by the Commission or an Agreement State to perform such services.
14. The licensee shall not perform repairs or alterations of the irradiator involving removal of shielding or access to the licensed material. Removal, replacement, and disposal of sealed sources in the irradiator shall be performed by a person specifically licensed by the Commission or an Agreement State to perform such services.
15. For each J. L. Shepherd and Associates, Mark I Cesium-137 Irradiator installed and used, the licensee shall:
- A. Permit the use of the irradiator only when a calibrated and operable radiation survey meter or room monitor is available; and
  - B. Permit the irradiator door to be opened only after the operator has checked visual indicators to verify that the source has returned to its safe storage position; and

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number

25-01203-01

Docket or Reference Number

030-05167

Amendment No. 34

15. (Continued)

C. Have room monitors installed that will:

- (i) Operate at all times when the irradiator is in use; and
- (ii) Activate a visible and audible alarm when radiation exceeds 2 millirems per hour; and
- (iii) Detect any radiation leaking from the irradiator door; and
- (iv) Be visible to the irradiator user when he is next to the irradiator; or

D. If a room monitor is not installed, have available a calibrated and operable survey meter which will be used to:

- (i) Determine the radiation level at the irradiation door when the door is closed; and
- (ii) Check for any increase in radiation levels each time the irradiator door is opened.

E. Not repair or authorize repairs of the irradiator except by the manufacturer or other persons specifically authorized by the Commission or an Agreement State to perform such services.

16. Licensed material shall not be used in or on human beings.

17. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.

18. The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license.

19. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash provided:

- A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.



MATERIALS LICENSE  
SUPPLEMENTARY SHEET

License Number

25-01203-01

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Amendment No. 34

19. (Continued)

- B. Before disposal as ordinary trash, byproduct material shall be surveyed at the container surface with the appropriate meter set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
  - C. A record of each disposal permitted under this License Condition shall be retained for 3 years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.
20. Pursuant to 10 CFR 20.1302(c) and 10 CFR 20.2002, the licensee is authorized to dispose of licensed material by incineration provided the gaseous effluent from incineration does not exceed the limits specified for air in Appendix B, Table II, 10 CFR Part 20.
21. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.
22. The licensee shall maintain records of information related to decommissioning at the address specified in item 2 above per the provision of 10 CFR 30.35(g) until this license is terminated by the Commission.

MATERIALS LICENSE  
SUPPLEMENTARY SHEET

License Number

25-01203-01

Docket or Reference Number

030-05167

Amendment No. 34

23. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Letter dated February 22, 1994
- B. Application dated January 18, 1994
- C. Letter dated November 22, 1994
- D. Letter dated December 9, 1994
- E. Letter dated December 16, 1996
- F. Letter dated February 25, 1997
- G. Letter dated March 18, 1997

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date MAR 26 1997

Original Signed By  
Vivian H. Campbell

By

Vivian H. Campbell  
Nuclear Materials Licensing Branch  
Region IV  
Arlington, Texas 76011



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION IV

611 RYAN PLAZA DRIVE, SUITE 400  
ARLINGTON, TEXAS 76011-8064

March 26, 1997

Department of Health & Human Services  
USPHS, NIH, NIAID  
Rocky Mountain Laboratories  
ATTN: Dianne Huhtanen  
Radiation Safety Officer  
903 South 4th Street  
Hamilton, Montana 59840

SUBJECT: LICENSE AMENDMENT

Please find enclosed License No. 25-01203-01, Amendment 34. You should review this license carefully and be sure that you understand all conditions. If you have any questions, you may contact the reviewer who signed your license at (817)860-8120.

NRC expects licensees to conduct their programs with meticulous attention to detail and a high standard of compliance. Because of the serious consequences to employees and the public which can result from failure to comply with NRC requirements, you must conduct your program involving radioactive materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Possess radioactive material only in the quantity and form indicated in your license.
3. Use radioactive material only for the purpose(s) indicated in your license.
4. Notify NRC in writing of any change in mailing address (no fee required if the location of radioactive material remains the same).
5. Request and obtain written NRC consent before transferring your license or any right thereunder, either voluntarily or involuntarily, directly or indirectly, through transfer of control of your license to any person or entity. A transfer of control of your license includes not only a total change of ownership, but also a change in the controlling interest in your company whether it is a corporation, partnership, or other entity. In addition, appropriate license amendments must be requested and obtained for any other planned changes in your facility or program that are contrary to your license or contrary to representations made in your license application, as well as supplemental correspondence thereto, which are incorporated into your license. A license fee may be charged for the amendments if you are not in a fee-exempt category.

6. Maintain in a single document decommissioning records that have been certified for completeness and accuracy listing all the following items applicable to the license:
  - Onsite areas designated or formerly designated as restricted areas as defined in 10 CFR 20.3(a)(14) or 20.1003.
  - Onsite areas, other than restricted areas, where radioactive materials in quantities greater than amounts listed in Appendix C to 10 CFR 20.1001-20.2401 have been used, possessed, or stored.
  - Onsite areas, other than restricted areas, where spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site have occurred that required reporting pursuant to 10 CFR 30.50(b)(1) or (b)(4), including areas where subsequent cleanup procedures have removed the contamination.
  - Specific locations and radionuclide contents of previous and current burial areas within the site, excluding radioactive material with half-lives of 10 days or less, depleted uranium used only for shielding or as penetrators in unused munitions, or sealed sources authorized for use at temporary job sites.
  - Location and description of all contaminated equipment involved in licensed operations that is to remain onsite after license termination.
7. Submit a complete renewal application with proper fee, or termination request at least 30 days before the expiration date on your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of radioactive material after your license expires is a violation of NRC regulations.
8. Request termination of your license if you plan to permanently discontinue activities involving radioactive material.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation; imposition of a civil penalty; or an order suspending, modifying, or revoking your license as specified in the "General Statement of



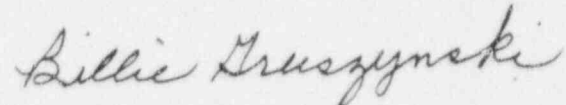
Department of Health and  
Human Services

-3-

Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), 60 FR 34381,  
June 30, 1995.

Thank you for your cooperation.

Sincerely,

A handwritten signature in cursive script that reads "Billie Gruszynski".

Billie Gruszynski (Ms.)  
Nuclear Materials Licensing Branch

Docket: 030-05167  
License: 25-01203-01  
Control: 466347

Enclosures: As stated

Department of Health and  
Human Services

-4-

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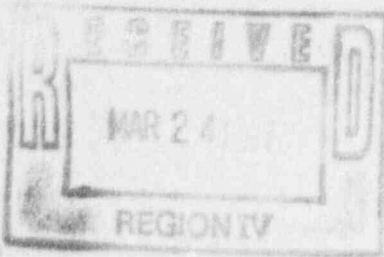
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BGruszynski <i>Bo</i>		VHCampbell <i>MC</i>					
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OFFICIAL RECORD COPY



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service



National Institutes of Health  
Rocky Mountain Laboratories  
Hamilton, Montana 59840  
(406) 363-3211  
FTS (700) 322-8400

March 18, 1997

U.S. Nuclear Regulatory Commission  
Region IV  
Material Radiation Protection Section  
Attn: Vivian Campbell  
611 Ryan Plaza Drive, Suite 400  
Arlington, TX 76011-8064

RE: License Amendment

Dear Ms. Campbell:

I am writing in reference to your letter of March 3, 1997, License No. 25-01203-01, and Amendment No. 33. According to the RML Radiation Safety Manual (page 5), the Chairman of the Radiation Safety Committee will be the Radiation Safety Officer. Therefore, please correct item 11.A. to read Dianne Huhtanen, Chairman.

Thank you for your attention to this matter.

Sincerely,

Dianne Huhtanen  
Radiation Safety Officer  
Rocky Mountain Laboratories

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